

REMARKS

Claims 94-170 are now pending in the above-referenced patent application. Of these, claims 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, 151, 152, 158 and 163 have been considered on the merits. Claims 104, 105, 108-111, 113, 114, 117-120, 122, 125, 128, 146-150, 153-157 and 159-162 have been withdrawn from consideration as being drawn to a non-elected species. New claims 164-170 read on the elected species, and are therefore likewise entitled to consideration on the merits. Applicants respectfully request further consideration of the claims, in view of the amendments set forth above and the following remarks.

Amended Claims

Claim 94 has been amended, without narrowing the scope thereof, to clarify that the method is directed towards *preparing* an array of non-biological polymer materials.

No new matter has been added.

New Claims

New claims 164-170 have been added to claim certain preferred embodiments of the invention. Support for new claims 164-165 can be found in original claims 44-47 and 49 and throughout the specification, including for example at page 39, lines 23-25, referencing Table 1 at pages 40-41. Support for new claims 166-170 can be found in the specification, including for example at page 36, lines 17-21 and at page 37, lines 25-28 (heating), at page 36, lines 25-30 (mixing), and at page 37, lines 23-25 (pressurizing).

As noted, each of these new claims read on the elected species. Therefore, further consideration of the new claims on the merits is appropriate.

No new matter has been added.

Rejections Under 35 U.S.C. § 112 (New Matter / Written Description / Enablement)

The Office action rejects claim 163 under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, as being new subject matter which was not adequately described in the specification. In particular, it is alleged that “there is *no indication* that the specific combination set forth in claim 163 was contemplated.” (See paragraph 6 at page 3 of the Office action).

The Office action also rejects each of claims 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, 151, 152, 158 and 163 as containing subject matter which was not adequately described in the specification. Specifically, the Office action alleges that certain aspects of the invention are broadly defined (*e.g.*, non-biological organic polymers), and asserts that the disclosure does not support the claimed genus or substantial portion thereof, and is therefore inadequate to show possession of the invention. (*See* paragraph 7 at pages 3-5 of the Office action).

Further, the Office action rejects each of claims 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, 151, 152, 158 and 163 as being non-enabled by the specification. Specifically, it is alleged that one skilled in the art would not have been able to make and/or use the invention as claimed without undue experimentation. (*See* paragraph 8 at pages 5-8 of the Office action).

Applicants respectfully traverse these grounds of rejection, in view of the amendments to the claims and the following remarks.

*The Specification Fully Supports the Inventions Defined by the Presently-Pending Claims*

Applicants respectfully submit that each of the pending claims are supported by the entirety of the specification as filed. Specifically, a skilled artisan would have recognized that Applicants were in possession of the invention, as presently claimed, at the time the original parent application was filed. Moreover, a person of skill in the art would have been enabled to make and use the presently-claimed invention at the time such application was filed.

The invention is directed, *inter alia*, to forming arrays comprising different non-biological polymers by delivering monomers (or in some claims, co-monomers) to different regions of a common substrate, and then simultaneously polymerizing to form different polymers at the different regions. Certain claims require a further screening step for evaluating the resulting polymers. Significantly, a person of ordinary skill in the art would have recognized that Applicants' invention represents new formats, approaches and protocols for investigating (*e.g.*, discovering and/or optimizing) non-biological polymeric materials – generally, and without regard to particular polymerization chemistries. A skilled artisan would have recognized, therefore, that the invention can be effected with existing, known polymerization chemistries.

The specification undeniably establishes that the Applicants considered their invention to include methods for creating and screening libraries of non-biological organic polymers, including a number of specifically-mentioned types of polymers. In particular, the specification sets forth the following description under the heading "Summary of the Invention":

The present invention provides methods and apparatus for the preparation and use of a substrate having an array of diverse materials in predefined regions thereon. ... (M)aterials which can be prepared include... non-biological organic polymers,... . Once prepared, these materials can be screened in parallel for useful properties including, for example,...chemical and other properties. As such, the present invention provides methods and apparatus for the parallel synthesis and analysis of novel materials having new and useful properties.

*See* page 4, lines 8-22 of the specification (emphasis added). *See also*, generally, page 12, line 1 to page 13, line 5.

Notably, in particular with respect to claim 163, the specification specifically and unambiguously identifies a substantial number of polymer types for which the present invention was considered to be applicable:

Examples of polymers which can be prepared using the methods of the present invention include, but are not limited to, the following: polyurethanes, polyesters, polycarbonates, polyethyleneimines, polyacetates, polystyrenes, polyamides, polyanilines, polyacetylenes, polypyrroles, *etc.*

*See* page 11, lines 16-20 of the specification (emphasis added). Also, in connection with these examples, the specification teaches that the polymers of the invention can be homopolymers, copolymers or higher-order polymers. *See* page 11, lines 10-13.

General methodologies for preparing such arrays are also set forth in the Office action. Specifically, the specification teaches that

the array of materials is prepared by successively delivering components of materials to predefined regions on a substrate, and simultaneously reacting the components to form at least two materials. In one embodiment, for example, a first component of a first material is delivered to a first region on a substrate, and a first component of a second material is delivered to a second region on the same substrate. Thereafter, a second component of the first material is delivered to the first regions on the substrate, and a second component of the second material is delivered to the second region on the substrate. Each component can be delivered in either a uniform or gradient fashion... The process is repeated, with additional components, to form a vast array of components at predefined, *i.e.*, known, locations on the substrate. Thereafter, the components are simultaneously reacted to form at least two materials. As explained hereinbelow, the components can be sequentially or simultaneously delivered to predefined regions on the substrate using any

of a number of different delivery techniques. ... (T)he components, after being delivered to predefined regions on the substrate, can be reacted using a number of different synthetic routes. For example, the components can be reacted using, for example, ... polymerization techniques... .

See page 13, lines 6-31 of the specification (emphasis added). The specification also teaches, more specifically with respect to the preparation of arrays of organic polymers, that

organic polymers can be prepared by delivering a monomer (or monomers) of interest to predefined regions on the substrate usually in the form of a solution. Once the monomer of interest has been delivered, an initiator is added to each region on the substrate. The polymerization reaction is allowed to proceed until the initiator is used up, or until the reaction is terminated in some other manner. Upon completion of the polymerization reaction, the solvent can be removed by, for example, evaporation *in vacuo*.

See page 38, lines 27-33 of the specification (emphasis added). Additionally, Applicants disclose, at page 39, line 27 to page 40, line 6 of the specification, that

(t)he properties listed in Table I can be screened for using conventional methods and devices... .

(emaphasis added). One of the specifically-included categories of properties recited, and further delineated in Table I is a chemical property. (See page 40-41). Hence, a person of skill in the art would have recognized that Applicants were in possession of the inventions defined by the presently-pending claims.

Significantly, the scope of the presently-pending claims are entirely consistent with the scope of the invention as disclosed in the specification. In such a situation, with respect to written description concerns,

(t)he Examiner has the initial burden of presenting evidence or reasons *why* persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.

See *In re Wertheim*, 191 USPQ90, 96 (CCPA 1976) and MPEP § 2163.04 (emphasis added). Likewise, with respect to enablement concerns,

it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

*See In re Marzocchi*, 169 USPQ 367, 369, 370 (CCPA 1971) and MPEP § 2164.04 (emphasis in original).

In the present case, however, the Office action sets forth only conclusory statements alleging a lack of support in the specification. As discussed below, the Office action does not present evidence or delineate sound reasons as to why the specification is considered to lack support. As such, the Applicants respectfully assert that the Office action does not establish, *prima facie*, that the specification lacks support under 35 USC 112.

#### *Claim 163 – Written Description*

With regard to claim 163, the position set forth in the Office action is completely unfounded.

As noted above with reference to page 11, lines 16-20, the specification expressly and unambiguously indicates that polycarbonates are among the specific types of polymers contemplated in connection with the generally-taught methods of the invention. As such, the Office action assertion that “there is *no indication* that the specific combination set forth in claim 163 was contemplated” is completely without basis. In fact, there is an *explicit* indication of the combination.

The Office action argues further, in this regard, that “a broad disclosure is **not** sufficient support for a specific entity within the class.” (See paragraph 6 at page 3 of the Office action (emphasis in original)). Although this may be an accurate reflection of the law in situations where the specific entity is *not disclosed*, this statement of the law does not apply to the facts at issue here, where each of the specific features recited in the claim are *expressly disclosed* in the specification, and a person of ordinary skill in the art would have understood that Applicants considered their invention to include the combination of such features.

Here, a person of ordinary skill in the art would have reasonably understood that Applicants were in possession of the invention defined by claim 163. As noted above, there is an express and unambiguous disclosure of polycarbonates as being of a preferred type of non-biological polymer. Moreover, a person skilled in the art would have understood with reasonable clarity that Applicants considered their invention to include each of the remaining requirements of claim 163 in combination. This is evidenced by various blazemarks that link the claimed features throughout the specification. For example, particular types of substrates, including

plate-type substrates, are disclosed at page 17, lines 7-27 (especially lines 9-12), and are expressly indicated as being useful in connection with preferred embodiments of the invention directed towards methods – like the method of claim 163 – for preparing an array of diverse materials at known locations on a single substrate surface. The specification, in its entirety, teaches a skilled artisan that the materials (*e.g.*, non-biological organic polymers) can be prepared on a substrate without covalently bonding the materials to the substrate. Delivery systems involving dispensers such as pipettes are likewise disclosed as being suitable in connection with such methods. *See*, for example, page 5, lines 15-26 (especially lines 24-26), and page 29, line 24 through page 36, line 12 (especially page 29, lines 27-32). Further, it is clearly contemplated that such liquid dispensers can be used to simultaneously deliver reactant components to multiple predefined regions of the substrate. (*See* page 32, lines 20-24). The specification also teaches that the reactions can be effected using pressurized gas reactant components for the recited synthesis routes (*e.g.*, including polymerization) of the invention. (*See* page 37, lines 23-25). Finally, the General Overview of the invention includes a generally-applicable discussion relating to individual control of reaction conditions at different reaction regions. (*See* page 14, lines 2-3. Specific types of reaction conditions that can be controlled and/or controllably varied are also expressly and unambiguously disclosed. (*See* page 14, lines 3-6 and page 5, lines 10-14). In view of such explicit teaching, there is no question that Applicants had possession of the invention defined by claim 163.

Applicants note, moreover, that claim 163 was filed in response to the election of species requirement set forth in the previous Office action. It seems disingenuous, at best, for the Office to require Applicants to elect a particular species from various species *articulated by the Office*, and then to take the position that claims drawn specifically to the elected species are not adequately described in the specification. Presumably, in articulating the requirement for election of species that includes various features, the Office *must* have considered Applicants to have been in possession of the invention defined by the combination of those features.

Accordingly, the basis for rejection of claim 163 is not substantiated by the facts, and should therefore be withdrawn.

*The Office's Reliance on Eli Lilly is Misplaced*

In rejecting all of the considered claims due to lack of written description, the Office action posits, *inter alia*, that the specification does not contain adequate representative examples to provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that applicant had possession of the full scope of the invention. The Office relies on *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) as authority for its position.

However, the Office's reliance on *University of California v. Eli Lilly and Co.*, ("*Eli Lilly*") and the other cases cited in the Office action is misplaced. This case is simply not controlling in connection with the facts of the instant patent application. In the *Eli Lilly* case, the claims were composition of matter claims directed to a genus of new biological compounds (*i.e.*, recombinant plasmids, or recombinant micoroganisms) defined primarily by biological functionality (*i.e.*, the capability of mRNA or cDNA to encode insulin). The specification at issue in the *Eli Lilly* case disclosed the protein which the cDNA compound was to encode, as well as a method for obtaining the mRNA or cDNA compounds. The specification did not, however, disclose the mRNA or cDNA compounds *per se*. A lack of written descriptive support was found since the specification did not include a description of a structure or other identifying indicia that would distinguish members of that genus, or allow the genus to be visualized or recognized by a person of skill in the art.

In the present application, unlike *Eli Lilly*, the claims are methods claims directed to novel methods for preparing and/or evaluating non-biological polymeric materials. Although the claimed methodologies involve the preparation of non-biological organic polymers on a substrate as one step of the method, the claimed subject matter is not the genus of non-biological organic polymer molecules as a composition of matter.

These differences are significant under the law, because method claims may require the *preparation or use* of certain known classes of materials by reference to the *genus* that defines such class – without having to recite multitudes of representative *species* within that genus.

Moreover, the Federal Circuit has repeatedly and soundly rejected broad, indiscriminate application of *Eli Lilly* as a basis for holding that methods claims lack written descriptive support. In *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 65 USPQ2d 1385 (Fed. Cir. 2003), for

example, the defendant challenged the validity of method claims directed toward a process for producing a particular recombinant polypeptide using vertebrate cells or mammalian cells as host cells. The basis of the defendant's challenge was that the patent owner (Amgen) had failed to sufficiently describe the use of all vertebrate and mammalian cells. The court rejected this challenge. Specifically, the court reasoned that

Both *Eli Lilly* and *Enzo Biochem* (63 USPQ2d 1613, Fed. Cir. 2002) are inapposite to this case because the claim terms at issue here are not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend. Instead, the claims of Amgen's patents refer to types of cells that can be used to produce recombinant human EPO. ... This difference alone sufficiently distinguishes *Eli Lilly*, because when used, as here, merely to identify types of cells (instead of undescribed previously unknown DNA sequences), the words "vertebrate" and "mammalian" readily "convey distinguishing information concerning their identity" such that one of ordinary skill in the art could "visualize or recognize the identity of the members of the genus."

(emphasis added; internal citations omitted). Thus, the court in *Amgen* held that the process claims were not invalid for failing to sufficiently describe all vertebrate and mammalian cells that that can be employed in the claimed method.

More recently in *Moba B.V. v. Diamond Automation, Inc.*, the Federal Circuit addressed the *Eli Lilly* decision in the context of an invention directed to methods for processing eggs. The court rejected a broad indiscriminate application of *Eli Lilly*, and again rearticulated the well-established standards for determining whether the written description requirement of 35 U.S.C. §112 is satisfied, to wit:

(one) should determine whether a person of skill in the art would glean from the written description... (information) sufficient to demonstrate possession of the generic scope of the claims. ...

(T)he applicant must convey, with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. ...

The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, instead the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.

(emphasis added, internal citations omitted).



The facts of the instant application are clearly in line with those of the *Amgen* and the *Moba* decisions of the Federal Circuit, and are clearly distinguished from *Eli Lilly*. Like the *Amgen* case, Applicants claims are method claims that involve the preparation and/or use of a generically-defined material (an array of non-biological organic polymers) – on a common substrate, and the subsequent screening of such materials. Here, as in *Amgen*, the claim terms at issue are not new or unknown materials that ordinarily skilled artisans would easily miscomprehend. Instead, as in *Amgen*, the presently-pending claims refer to types of materials that can be used in connection with a process to evaluate non-biological organic polymer materials. This difference sufficiently distinguishes *Eli Lilly*, because here, as in *Amgen*, the terms are being used merely to identify types of materials for use in the claimed process – not to identify *undescribed, previously unknown* compounds. In short, the words “non-biological organic polymers” readily convey distinguishing information concerning their identity such that one of ordinary skill in the art could visualize or recognize the identity of the members of the genus. The law requires nothing further.

Accordingly, the basis for rejection of the pending claims should be withdrawn because it incorrectly applies the law to the facts at hand.

#### *Enablement*

Contrary to the position asserted in the Office action, a person of ordinary skill in the art would have been able to practice the inventions defined by the claims without undue experimentation.

In particular, the Office action has misapplied many of the factors set forth in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) for analysis of whether a person of ordinary skill in the art would have been able to practice Applicants invention without undue experimentation. For example, the Office action has considered the *breadth of the claims*, but has apparently completely ignored the *nature of the invention*. In this regard, a person of ordinary skill in the art would have appreciated that the invention defined by the instant claims relates to a protocol involving a format for preparing and screening arrays of non-biological organic polymers – that is completely general to, and independent of, the particular types of polymerization chemistries (e.g., polymer structures) and polymerization reactions. Accordingly, the concerns expressed in the Office action relating to the scope of the polymer structure and to the inherent uncertainty of

polymerization chemistries and reactions is misplaced in this instance. In fact, it is the inherent unpredictability in the art that makes Applicants' invention particularly useful – because it provides a protocol and format that offers significant advantages for investigating polymers and polymerization reactions. Further, the asserted need for a broad range of examples that demonstrate the use of Applicants invention across a broad range of polymerization reactions is likewise misplaced – both legally and factually. The law explicitly holds that “(n)othing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). Further, considered factually, the Office's position is misplaced in view of the *state of the art* (acknowledged as being highly developed for polymerization), the *level of skill in the art* (acknowledged as being relatively high) and the *level of guidance* provided in the specification. In this latter aspect, the Office action appears to selectively focus on certain aspects of the claim (*e.g.*, polymer structure), while disregarding other significant and characterizing aspects of the claims (*e.g.*, polymerization in an array format) for which substantial *guidance* is clearly provided in the specification – as discussed below. Hence, complete and accurate consideration of the *In re Wand* factors clearly demonstrate that a skilled person could practice the instant inventions without undue experimentation.

Contrary to assertions made in the Office action,<sup>1</sup> the specification provides substantial guidance with respect to the defining features of the invention, as claimed – the preparation of diverse polymeric materials in a spatially addressable, common-substrate format. With further reference to the passages noted above, an overview of general and specific approaches is provided (*See* page 12, line 1 through page 17, line 4 of the specification), together with specific details regarding various component-delivery approaches. Among others, gas-phase chemical processes and liquid-phase chemical processes and deposition techniques are disclosed in significant detail. These techniques are particularly suited to delivery of monomers, including delivery techniques for solution-phase monomers (*e.g.* with a dispenser), and are expressly taught as being suitable for delivery of non-biological polymeric components. (*See*, for example,

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<sup>1</sup> In particular, Applicants expressly disagree with the unfounded, conclusory allegations made in the Office action that the specification does not provide a “generic strategy”, and provides “no indication” for preparing and evaluating an array of polymers. Such statements are factually incorrect, as described in response herein, and as such, do not satisfy the Examiner's burden as set forth in *In re Marzocchi et al.*, *supra*.

page 29, line 24 through page 36, line 12 of the specification.) The specification also describes various approaches for isolation of predefined regions (*See*, for example, page 17, line 6 through page 22, line 6 of the specification). Reaction of monomers and optionally other delivered components is also particularly described with respect to non-biological polymeric materials. (*See*, for example, page 38, line 27-33 of the specification). Various reaction protocols that are particularly effective in connection with bulk polymerization reactions, such as stirring and/or pressurizing and/or heating during the reaction, are likewise disclosed. (*See*, for example: page 36, lines 17-21 and page 37, lines 25-28 (heating); page 36, lines 25-30 (mixing); and page 37, lines 23-25 (pressurizing)). Intermittent reaction processing steps are likewise disclosed. (*See*, for example, page 37, line 29 through page 38, line 3. The specification further teaches that the arrays of non-biological polymeric materials can be screened according to many specifically-known techniques for specifically-known properties of interest. (*See*, for example, page 39, line 6 through page 43, line 31 of the specification). Moreover, as acknowledged in the Office action, the preparation of an array of non-biological polymers is exemplified in Example B – and expressly demonstrates the invention defined by the presently-pending claims.

In view of such guidance, especially when coupled with the vast warehouse of knowledge existing in the art related to specific polymerization reactions of interest,<sup>2</sup> a person of ordinary skill would have been enabled to apply Applicants' teaching to the specific polymerization chemistries and reactions of interest without undue experimentation.

In particular, the Examiner's position with regard to enablement of claim 163 is particularly troubling. The rationale set forth in the Office action with regard to enablement is largely, if not completely inapposite to the more narrowly-drawn invention defined by claim 163. As such, under *In re Marzocchi, supra*, the Office action does not set forth a *prima facie* case of non-enablement with regard to claim 163. The Office action acknowledges that claim 163 recites

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<sup>2</sup> The Office action expressly acknowledges that there is a substantial body of art related to polymer synthesis and testing. (*See* paragraph 13 of the Office action). It is well settled that the specification must be considered in view of that which is already known in the art, and as such, that Applicants need not describe, and preferably omit, that which is well known in the art. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986). Also, the Office action articulates concern that the claimed genus could encompass members that are yet to be prepared or envisioned. (*See* paragraph 7, at page 5 of the Office action). However, the law is clear that such observation is irrelevant to the analysis under 35 U.S.C. §112. *See In re Hogan*, 194 USPQ 527, 537-538 (CCPA 1977) (holding that Applicants are not required to support *later* improvements in the art, even if such improvements are patentably distinct); *see also U.S. Steel Corp. v. Phillips Petroleum Co.*, 9 USPQ2d 1461 (Fed. Cir. 1989).

a specific structure, but appears to suggest that since that structure is alleged to lack descriptive support, that it is likewise not enabled. This is not the law. A claimed invention can be fully enabled, even if, *arguendo*, that specific invention lacks descriptive support in the specification. These are two separate requirements of the law under 35 U.S.C. §112.

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Therefore, since the inventions as claimed are adequately described and fully enabled by the specification, all of the rejections under 35 U.S.C. § 112 should be withdrawn.

Rejections Under 35 U.S.C. § 112 (Indefiniteness)

The Office action rejects claims 94-103, 106, 107, 111<sup>3</sup>, 115 and 116 under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, as being indefinite. Specifically, the preamble of claim 94 is said to be inconsistent with the steps recited in the body of the claim. (*See* paragraph 10 at pages 8-9 of the Office action).

Applicants respectfully submit that this basis for rejection has been obviated in view of the amendment to claim 94.

Rejections Under 35 U.S.C. § 103(a)

The Office action rejects claims 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, 151, 152 and 158 under 35 U.S.C. § 103(a) as being obvious based on Rolleston *et al.* (U.S. Patent No. 5,416,613) and Howard *et al.* (U.S. Patent No. 3,868,221) in view of Baldeschweiler *et al.* (U.S. Patent No. 5,847,105) and Leasure *et al.* (1994) and Gallop *et al.* (1994). (*See* paragraph 13 at pages 10-13 of the Office action.) Specifically, Rolleston *et al.* are relied upon in the Office action said to show that “arrays of materials for testing were well known at the time of filing.” *Id.* Howard *et al.* are relied upon to show that “testing of polymers was well known”. *Id.* Baldeschweiler *et al.* are said to teach “a method for the synthesis of arrays of chemical compounds,” and “that small molecules can be made,” but the Office action expressly acknowledges that Baldeschweiler *et al.* does not teach methods for preparing arrays of non-biological organic polymers. *Id.* Leasure *et al.* is said to disclose the preparation of spatially

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<sup>3</sup> *Cf.*, Claim 111 was withdrawn from consideration as being drawn to a non-elected species.

defined arrays of polymeric materials using lithography. *Id.* Gallop *et al.* is said to teach the “general tenets of combinatorial chemistry.” *Id.*

Applicants respectfully traverse these rejections.

*The Present Invention, Considered as a Whole, Would Not Have Been Obvious*

A determination of obviousness must consider the claimed invention as a whole. That is, “in determining the differences between the prior art and the claims, the question under 35 USC 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.” See MPEP 2141.02 and Stratoflex, Inc. v. Aeroquip Corp., 218 USPQ 698 (Fed. Cir. 1983) (emphasis in original); See also, for example, Grain Processing Corp. v. American Maize-Products Co., 5 USPQ2d 1788 (Fed. Cir. 1988) (stating that “the inquiry is not whether each element existed in the prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed.” *citing* Hartness Int'l, Inc. v. Simplimatic Eng'g Co., 2 USPQ2d 1826 (Fed. Cir. 1987); Ecolochem, Inc. v. Southern California Edison Company, 56 USPQ2d 1065 (Fed. Cir. 2000).

The inventions defined by the presently-pending claims are directed to methods for preparing, and in some embodiments, screening arrays of materials. Specifically, the arrays comprise non-biological organic polymers situated on a substrate (or equivalently, at or in a substrate), where the non-biological organic polymers are different from each other (*e.g.*, with respect to composition, physical properties, polydispersity, *etc.*). In some embodiments, the arrays are screened for specific properties of interest – including especially for example, thermal, mechanical, chemical, morphological and/or optical properties. Other particular aspects of the inventions are discussed in detail below.

Applicants have developed a novel, high-throughput approach for screening polymeric materials outside of the biological / pharmaceutical context. This approach can be directed, for example, to various specialty polymer fields to discover novel non-biological polymers having a desired property or a set of properties – fields for which high-throughput experimentation techniques had not been previously developed. Although high-throughput research approaches had been developed for other fields (*e.g.*, in connection with biotechnological research (*e.g.*, oligonucleotides, polypeptides) and pharmaceutical research (*e.g.*, small organic

molecules)), the approaches employed in such fields were not – prior to Applicants inventions – extended in the manner defined by the presently-pending claims.

Hence, as discussed in greater detail below, the present invention – properly considered as a whole – cannot be considered obvious over the prior art of record.

*There is No Motivation Existing In the Art*

There is no motivation existing in the art that would have led a skilled artisan to combine the teaching of the various references in a manner that would have led to the claimed inventions. The Office action fails to set forth any reasoning as to why a person of ordinary skill in the art would have been motivated to combine the cited references – Rolleston *et al.*, Howard *et al.*, Baldesweiler *et al.*, Leasure *et al.* and Gallop *et al.* As such, the Office action fails to establish a *prima facie* case of obviousness. In view of the repeated warnings by the Federal Circuit against hindsight reconstruction (*i.e.*, against finding the required motivation in the guidance of the instant specification), the inventions defined by these claims cannot be considered to be obvious. See, for example, *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

The primary references relied upon in the Office action – Rolleston *et al.* and/or Howard *et al.*, would not have led a skilled artisan to Applicants' invention.

Rolleston *et al.* disclose an array of color patches (*e.g.*, *pigments*) on a paper substrate, and use thereof for printer calibration – that is, for determining the performance of the *printer* as compared to known, device-independent standards – not for evaluating or determining the relative performance of the *materials*. Accordingly, a skilled artisan would not have been motivated by the Rolleston *et al.* to prepare arrays of diverse *non-biological organic polymers* according to the methods claimed herein, and moreover, would not have been motivated to use such arrays to *evaluate materials* for identifying those materials having useful properties, as part of a materials discovery or optimization program. Because the Rolleston *et al.* reference is unrelated to organic polymeric materials, and is used for a completely different purpose than Applicants' invention, it's relevance to Applicant's invention is difficult to appreciate – without hindsight.

Howard *et al.* would likewise not have motivated a skilled artisan to practice Applicants' invention. Howard *et al.* disclose protocols and apparatus for testing the resistance of polymers to thermal degradation at elevated temperatures. Significantly, however, Howard *et al.* do not

disclose the preparation of polymer samples on a common substrate. Rather, samples are provided for analysis in individual containers. As such, Howard *et al.* represents *traditional* approaches to polymer research, and would not have led a person of ordinary skill to Applicants' invention. In fact, absent hindsight, Howard *et al.* would have taught away from Applicants' invention, by preserving the then-existing bias in the art for traditional, bench scale polymerization research.

Hence, Applicants' inventions – when properly viewed as a whole – would not have been considered to be obvious over Rolleston *et al.* and/or Howard *et al.*, considered alone, or in combination with each other.

The Baldeschweiler *et al.*, Leasure *et al.* and/or Gallop *et al.* do not make up for the deficiencies of Rolleston *et al.* and/or Howard *et al.*. Applicants note, preliminarily, that previous rejections under §103(a) in the parent case – based on Baldeschweiler *et al.*, in view of Leasure *et al.* and, independently, based on Baldeschweiler *et al.* in view of Gallop *et al.* – have already been addressed and subsequently withdrawn in view of Applicants remarks in response thereto.<sup>4</sup> The Examiner is respectfully referred to Applicant's previous remarks regarding these references, supplemented herein as follows.

Briefly, as acknowledged in the Office action, Baldeschweiler *et al.* does not disclose, teach or suggest arrays comprising non-biological organic polymers. Gallop likewise does not disclose such polymers. Leasure does not teach arrays comprising different materials, and as noted in the Office action, uses *lithographic* techniques, rather than bulk polymerization techniques. Nonetheless, the Office action does not set forth any convincing basis as to why a skilled artisan would modify such references to achieve Applicants' invention.

The Office action states that “the advantages (*e.g.*, relatively fast and efficient easy assays, etc.) and application of parallel combinatorial arrays for generating and optimizing properties were known in the prior art.” (*See* paragraph 13 at page 12 of the Office action). Applicants concede that combinatorial (*i.e.* high-throughput) research approaches had been developed in connection with biotechnological research (*e.g.*, oligonucleotides, polypeptides) and pharmaceutical research (*e.g.*, small organic molecules). However, even if such generalized

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<sup>4</sup> Applicants remarks should not be considered as an admission that the Baldeschweiler *et al.*, Leasure *et al.*, and/or Gallop *et al.* references are statutory prior art to the instant invention. Applicants expressly reserve the right to submit evidence that Applicants invented the subject matter defined by the claims before the filing and/or publication dates of these references.

advantages were recognized as applied to those fields of research, this does not establish the requisite level of motivation for *prima facie* obviousness. Such broadly viewed advantages are too general to motivate a skilled artisan to arrive at the specific invention defined by these claims. See In re Fine, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Dow Chemical Co., 5 USPQ2d 1529 (Fed. Cir. 1988); In re Geiger, 2 USPQ2d 1276 (Fed. Cir. 1987). The law requires a more specific suggestion in the art than merely the commonality of advantages, as recognized in hindsight.

The Office action also states that “(a) person of ordinary skill in the art would have been motivated to do [sic: so] to have an array of materials for testing to find compounds of interest.” (See paragraph 13 at page 12-13 of the Office action). Such a basis is likewise inadequate and does not establish the requisite motivation. The rationale provided is again too general – and absent impermissible hindsight, is not specific enough to lead a person of ordinary skill to the particularly recited invention as claimed (*i.e.* to preparing and evaluating non-biological polymers according to the particularly recited protocols of Applicants’ invention). Additionally or alternatively, to the extent that such statement was intended to refer more specifically to non-biological polymers, the statement clearly represents hindsight analysis. In view of the repeated warnings by the Federal Circuit against hindsight reconstruction (*i.e.*, against finding the required motivation in the guidance of the instant specification), Applicants respectfully submit that such extrapolation is improper under the law. See, for example, Grain Processing Corp. v. American Maize-Products Co., 5 USPQ2d 1788 (Fed. Cir. 1988) (stating that obviousness cannot be established by merely showing that each element of the patented products may be found somewhere in the prior art). See also In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991), and In re Dembiczak, 50 USPQ2d, 1614 (Fed. Cir. 1999).

Obviousness cannot be established based merely on the fact that the reference *could* have been combined or modified, unless the prior art also suggests the desirability of the combination. In re Mills, 16 USPQ2d 1430 (Fed. Cir. 1990). Without an improper hindsight reconstruction of Applicants’ invention – by picking and choosing from among the various cited references – there is no basis for combining these references as required to arrive at Applicants’ invention.

Additionally, the cited references do not establish obviousness of the pending claims in view of particularly required features thereof, including for example, inventions characterized by one or more of the following features: polymerization of monomers without stepwise, coupling



of such monomers – that is, without a series of separately controlled individual reactions; independently and controllably varying the polymerization reaction conditions between different regions of the substrate; and/or providing monomer components to respective regions of the substrate in a gradient of stoichiometries; and/or applying the methodologies for co-polymerizations or higher-order polymerizations.

Therefore, Applicants respectfully submit that the present invention would not have been obvious over the cited references.

#### Acknowledgement

Applicants acknowledge that the Office action does not set forth any prior-art basis for rejection of claim 163. Accordingly, subject to overcoming the rejections of this claim under 35 U.S.C. § 112, Applicants submit that this claim is in condition for allowance.

#### Equivalents

The amendments to the claims and the arguments presented in supplemental response to the Office action have been made to claim subject matter which the Applicants regard as their invention. By such amendments, the Applicants in no way intend to surrender any range of equivalents beyond that which is needed to patentably distinguish the claimed invention as a whole over the prior art. Applicants expressly reserve patent coverage to all such equivalents that may fall in the range between applicants literal claim recitations and those combinations that would have been obvious in view of the prior art. In particular, as noted above, claim 94 has not been narrowed within the meaning of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 62 USPQ2d 1705 (2002), and Applicants are therefore entitled to the full range of equivalents with respect thereto.

#### CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

The Examiner is hereby authorized to charge the fees required in connection with this Amendment C to Deposit Account No. 50-0496, in accordance with the Transmittal submitted herewith. The Examiner is also authorized to debit any other fees required in connection with

this application, or to credit any overpayment of fees in connection with this application to  
Deposit Account No. 50-0496.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul A. Stone". The signature is stylized with a large, looping initial "P" and a distinct "A".

Date Submitted: Oct. 9, 2003

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